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THERAVANCE, INC.
901 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER
BAKER, MAURIE GARCIA

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 29

Application Number: 09/457,926
Filing Date: December 8, 1999
Appellant(s): Christensen et al

Jeffrey A. Hagenah
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed December 13, 2002.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: Appellant states that the issue is whether "Claims 41-46, 49-51, 53-55, 57 and 58 are unpatentable under 35 U.S.C. 103(a)". As correctly stated in the ***Status of Claims*** section, only claims 41, 43, 49-51 and 53-55 are under examination, while claims 42, 44-46, 57 and 58 stand withdrawn from consideration as drawn to non-elected species. Thus the

statement of the issues should read --- whether Claims 41, 43, 49-51 and 53-55 are unpatentable under 35 U.S.C. 103(a) ---.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 46, 54, 57 and 58 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8). However, as stated in section (6) above, claims 46, 57 and 58 are not currently under examination (stand withdrawn from consideration). Therefore, only appellants remarks with regard to claim 54 have been addressed.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,693,791	Truett	12-1997

Boeckh, M. et al. "Pharmacokinetics and Serum Bactericidal Activity of Vancomycin Alone and in Combination with Ceftazidime in Healthy Volunteers." Antimicrob. Agents Chemother., Vol. 32, No. 1 (January 1988), pp. 92-95.

Renoud-Grappin, M. et al. "Imidazo[1,5-b]pyridazine-d4T Conjugates: Synthesis and Anti-Human Immunodeficiency Virus Evaluation." Antiviral Chem. and Chemotherapy, Vol. 9, No. 3 (May 1998), pp. 205-223.

Staroske, T. et al. "Synthesis of Covalent Head-to-Tail Dimers of Vancomycin." Tet. Lett., Vol. 39 (1998), pp. 4917-4920.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 41, 43, 49-51 and 53-55 are rejected under 35 U.S.C. 103. This rejection (from prior Office action, Paper No. 25) is set forth below:

Claims 41, 43, 49-51 and 53-55 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Truett (US 5,693,791; on PTO-1449) in view of Boeckh et al (Antimicrob. Agents Chemother., 1988, Vol. 32, No. 1, pp. 92-95; of record) and Renoud-Grappin et al (Antiviral Chem. and Chemotherapy, Vol. 9, No.3, 1998, pp. 205-223) and Staroske et al (Tet. Lett., 1998, Vol. 39; on PTO-1449).

Truett teaches the "linking of diverse antibiotic moieties via difunctional organic compounds" (see column 1, lines 8-9). Specifically, dimers are taught having the structure A-L-B, where A and B are various antibiotic moieties (see "Summary", columns 1-6, especially column 1, lines 46-64). A variety of linkers and linkage chemistries are taught (see columns 25-32). The reference teaches that the linkage of two antibiotic moieties can create compounds of new activity (see column 1, lines 1-30) and that "two antibiotic moieties can be linked in which one is known to attack Gram

positive bacteria and another to attack Gram negative bacteria" (see column 1, lines 27-30). Truett teaches a dimeric compound where one of the antibiotic moieties is ceftazidime (see column 3, line 7). Ceftazidime is a beta lactam antibiotic that reads on the elected species that is set forth in claim 53, see structure in the instant Figure 6B-2. Truett lacks the teaching of linking vancomycin with ceftazidime.

However, it was well known in the art at the time of filing to use combination therapy with vancomycin and ceftazidime. For example, Boeckh et al teach that this combination therapy is used to "cover a broad spectrum of gram positive and gram negative bacteria" (see page 92, 1st paragraph). The reference teaches the pharmacokinetics of the combination of vancomycin and ceftazidime, administered to humans (see Abstract and Table 1), thus pharmaceutical compositions of the drugs are well known.

Renoud-Grappin et al teach that one way to achieve effective combination therapy is to covalently link two different drugs. See page 208, first column, first full paragraph of the reference, which describes using heterodimers for combination therapy linked "through an appropriate spacer, in an attempt to combine the inhibitory capacity" of two different classes of molecules. The reference also describes that one would attempt such an approach to span two binding sites on the target. Renoud-Grappin et al also discuss combining different drugs to "prevent the emergence of drug-resistant virus strains" and set forth three main reasons for combination therapy (see page 207, 2nd column, 2nd paragraph). It is recognized that the linked compounds of

Renoud-Grappin et al (see, for example, Figure 4 of the reference) are anti-virals and not antibiotics; however, it is the examiner's position that one of ordinary skill would recognize the relevance of preventing the emergence of drug-resistant strains for both classes of molecules since such was well established in the art.

Additionally, vancomycin dimers were also known in the art at the time of filing. Staroske et al discuss both "head-to-head" and head-to-tail" dimers (see Figure 3) and that in "light of recent reports of vancomycin -resistant bacteria" there is a "strong incentive for the development of more potent antibiotics" (page 4917, bottom). The reference also teaches that dimeric vancomycin compounds exhibit improved antibacterial activity, see for example, page 4918, top. Specifically, the dimers of Staroske et al are linked from the amino terminus of one vancomycin moiety to the carboxy terminus of another (see Scheme 1, page 4919). The reference also contemplates linking of the vancomycin at the vancosamine moiety (see page 4920, last two paragraphs).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to link vancomycin and ceftazidime, based on the teaching of Truett concerning the linking of diverse antibiotic moieties combined with the teaching of Boeckh et al to perform combination therapy using the drugs, the teaching of Renoud-Grappin concerning linking drugs to perform combination therapy and the teaching of Staroske et al concerning vancomycin dimers linked through the amino and carboxy terminus. Specifically, Truett teaches that two antibiotics, one

known to attack Gram positive bacteria and another to attack Gram negative bacteria can be linked and the advantages of doing such, and Boeckh et al teach that vancomycin and ceftazidime fulfill these requirements. Renoud-Grappin teach that one way to achieve effective combination therapy is to covalently link two different drugs. Finally, Staroske et al teach that vancomycin can be linked at specific linkage sites. One of ordinary skill would have been motivated to covalently link vancomycin with ceftazidime to create a broad spectrum antibiotic compound to fight antibiotic resistant strains. One of ordinary skill would also have had a reasonable expectation of success based on the fact that Staroske et al teaches linking chemistry for vancomycin.

(11) Response to Argument

Appellant argues that there is insufficient motivation and no reasonable expectation of success (Points (1) and (2) from pages 6-7 of the Brief). However, the examiner maintains that one of ordinary skill in the art at the time of filing would have been motivated and had a reasonable expectation of success for the reasons set forth in the rejection and the further reasons below. Also, with respect to Point (3) on page 7 of the Brief, this will be addressed at the end of this section.

Motivation

Appellant addresses motivation on pages 8-16 of the Brief. First, appellant states that "Appellants' claimed compounds are not homologs, analogs or isomers of any of the prior art compounds of record" (Brief, page 8). The examiner agrees with this statement and notes that the rejection was not based on this particular fact pattern.

Instead, the claimed invention is deemed have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention based on the following rationale: it would have been obvious to one of ordinary skill to link vancomycin and ceftazidime, based on the teaching of Truett concerning the linking of diverse antibiotic moieties combined with the teaching of Boeckh et al to perform combination therapy using the drugs, the teaching of Renoud-Grappin concerning linking drugs to perform combination therapy and the teaching of Staroske et al concerning vancomycin dimers linked through the amino and carboxy terminus.

In this case, the examiner maintains that the *combined* teachings of the cited references

render the claimed invention obvious. "To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Also, the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). In the instant case, the beneficial result of the combination of references is creating a broad spectrum antibiotic compound to fight antibiotic resistant strains.

As stated in the rejection, Truett teaches that two antibiotics, one known to attack Gram positive bacteria and another to attack Gram negative bacteria can be linked and the advantages of doing such, and Boeckh et al teach that vancomycin and ceftazidime fulfill these requirements. Appellants do not agree with the examiner's interpretation of the teachings of Truett (Brief, page 9, bottom - page 10), arguing that "the Truett reference does not explicitly state any particular advantage" (Brief, page 10, top). The examiner's position is that the teachings of Truett, specifically that the linkage of two antibiotic moieties can create compounds of new activity (see column 1, lines 1-30) and that "two antibiotic moieties can be linked in which one is known to attack Gram positive bacteria and another to attack Gram

negative bacteria" (see column 1, lines 27-30) are sufficient to show the advantages of their approach.

Appellant goes on to argue that because this explicit advantage is lacking, the combination of Truett with Boeckh would lead one of ordinary skill to physical mixtures and not covalently linked dimers (Brief, Page 11). However, as appellant has pointed out (Brief, page 11, bottom - page 12), other references have been cited by the examiner to address the further motivation and show the state of the prior art. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus, the citation of the Renoud-Grappin reference was set forth in order to demonstrate the state-of-the-art with respect to combination therapy. As stated in the rejection,

> Renoud-Grappin et al teach that one way to achieve effective combination therapy is to covalently link two different drugs. See page 208, first column, first full paragraph of the reference, which describes using heterodimers for combination therapy linked "through an appropriate spacer, in an attempt to combine the inhibitory capacity" of two different classes of molecules. The reference also describes that one would attempt such an approach to span two binding sites on the target. Renoud-Grappin et al also discuss combining different drugs to "prevent the emergence of drug-resistant virus strains" and set forth three main reasons for combination therapy (see page 207, 2nd column, 2nd paragraph). It is recognized that the linked compounds of Renoud-Grappin et al (see, for example, Figure 4 of the reference) are anti-virals and not antibiotics; however, it is the examiner's position that one of ordinary skill would recognize the relevance of preventing the emergence of drug-resistant strains for both classes of molecules since such was well established in the art.

The examiner's position is that the above teachings with respect to combination therapy using covalently linked drugs (Renoud-Grappin) and the teachings of Truett regarding the actual synthesis of dimeric antibiotic compounds would have motivated one of ordinary skill to such a dimeric approach for vancomycin and ceftazidime since it was also well known in the

art at the time of filing to use combination therapy with vancomycin and ceftazidime (see teachings of Boeckh).

Appellants also argue that the Renoud-Grappin reference "teaches away from the preparation of dimers by demonstrating that the disclosed dimers did not provide any advantage" (Brief, page 12). See MPEP 2143.01: The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991).

Thus, the examiner's position is that although some aspects of the Renoud-Grappin reference may "conflict" with respect to the failure of the heterodimeric approach to achieve effective combination therapy, the reference *suggests solutions* to this failure: "chemists should explore other linkers and attachment sites for these linkers" (Renoud-Grappin, page 219, 2nd column, last paragraph). Also, although a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; "the nature of the teaching is highly relevant and must be weighed in substance" (see MPEP 2145). The examiner maintains that the teachings of the Renoud-Grappin reference still render the claimed invention obvious when considered *as a whole* and in the context of the rest of the prior art cited. Moreover, as is evident, the Renoud-Grappin reference actually teaches *toward*

appellant's invention since (1) it teaches a specific heterodimer that was not effective and (2) provides alternative solutions as to how to make an effective heterodimer, contrary to appellant's assertion.

With respect to the Staroske reference, this was cited to demonstrate that vancomycin dimers were also known in the art at the time of filing. Staroske et al discuss both "head-to-head" and head-to-tail" dimers (see Figure 3) and that in "light of recent reports of vancomycin -resistant bacteria" there is a "strong incentive for the development of more potent antibiotics" (page 4917, bottom). The reference also teaches that dimeric vancomycin compounds exhibit improved antibacterial activity, see for example, page 4918, top. Specifically, the dimers of Staroske et al are linked from the amino terminus of one vancomycin moiety to the carboxy terminus of another (see Scheme 1, page 4919). The reference also contemplates linking of the vancomycin at the vancosamine moiety (see page 4920, last two paragraphs).

Appellant argues that the Staroske reference also "provides little or no motivation to prepare dimers" (Brief, page 13). However, the examiner's position is that the teachings of the references render the claimed invention obvious when considered *as a whole*. Also, the Staroske reference was cited in particular to show that the linkage chemistry of vancomycin was established in the art and that linking of vancomycin to another antibiotic is a technique that is also art-established in the development of "more potent antibiotics" (Staroske, page 4917).

Lastly, appellant argues that the examiner has improperly derived the motivation to combine references from the instant specification (Brief, pages 15-16). Appellant argues that the examiner has used "Appellants' disclosure as a guide to pick the Boeckh reference from the vast array of prior art documents" (Brief, page 15). The examiner respectfully disagrees. The Boeckh reference is directed to appellant's ***elected species*** of L' and L" moieties. The examiner has followed MPEP § 803.02 with respect to species elections , which is quoted here in part (emphasis added):

> Following election, **the Markush-type claim will be examined fully with respect to the elected species** and further to the extent necessary to determine patentability. If the Markush-type claim is not allowable over the prior art, examination will be limited to the Markush-type claim and claims to the elected species, with claims drawn to species patentably distinct from the elected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species.

Also, in response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The examiner maintains that the combined teachings of the cited references indicate information that was within the level of ordinary skill and render the claimed invention *prima facie* obvious.

Expectation of success

Appellant addresses expectation of success on pages 16-21 of the Brief. First appellant argues that there is not a reasonable expectation that the proposed modification will succeed and that the proposed modification is unpredictable. Appellants particularly address teachings of the Renoud-Grappin reference with respect to the "failure of the dimer approach". As stated above, the examiner's position is that although some aspects of the Renoud-Grappin reference may "conflict" with respect to the failure of the heterodimeric approach to achieve effective combination therapy, the reference *suggests solutions* to this failure: "chemists should explore other linkers and attachment sites for these linkers" (Renoud-Grappin, page 219, 2nd column, last paragraph). Also, although a prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; "the nature of the teaching is highly relevant and must be weighed in substance" (see MPEP 2145). As pointed out above, the Renoud-Grappin reference can be interpreted as teaching *toward* appellant's invention since it offers clear guidance as to what heterodimers were not effective and then provides alternative solutions as to how to make an effective compound.

Also, note that "[o]bviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart,* 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). No ***evidence*** has been provided in support of applicant's conclusion that there is no reasonable expectation of success based on the teachings of the Renoud-Grappin reference. The examiner maintains that although the compounds of Renoud-Grappin did not

show an increase in inhibitory activity, the reference suggests solutions and maintains that the *combined* teachings of the references would have suggested the claimed invention to one of ordinary skill in the art.

Moreover, appellant's arguments do not rise to the level of factual evidence. See MPEP § 716.01(c): The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Also, it appears that appellant is arguing that their claimed dimeric antibiotic compounds have some sort of superior activity (see for example, Brief, pages 18-19) since they argue that one of ordinary skill would not have had a reasonable expectation of success, despite the evidence cited by the examiner in the form of the four prior art references. However, objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results... See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence"). Lastly, any differences between the claimed invention and the prior art may be expected to result in some differences in properties. The issue is whether the properties differ to such an extent that the difference is really unexpected. *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (In MPEP § 716.02).

In response to appellant's argument that the rejection represents only an "obvious to try" rationale (Brief, pages 19-21), the following from MPEP 2145 is noted:

> The admonition that obvious to try' is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be

successful. . . . In others, what was obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *In re O 'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (citations omitted) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.). See the cases cited in O 'Farrell for examples of decisions where the court discussed an improper "obvious to try" approach. See also In re Eli Lilly & Co., 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) and In re Ball Corp., 925 F.2d 1480, 18 USPQ2d 1491 (Fed. Cir. 1991) (unpublished) for examples of cases where appellants argued that an improper "obvious to try" standard was applied, but the court found that there was proper motivation to modify the references.

Appellant states that the claimed invention is directed to "novel chemical compounds having a specifically-defined chemical structure" (Brief, page 20, middle) and argue that the references represent only broad generalized teachings (Brief, page 21). The examiner respectfully disagrees. First, Truett teaches a variety of linkers and linkage chemistries (see columns 25-32) that read on the claimed X' moiety. The Truett reference also specifically teaches ceftazidime (a beta lactam antibiotic that reads on the elected species) see structure in the instant Figure 6B-2. Also, Boeckh teaches combination therapy *specifically using* vancomycin and ceftazidime and Staroske teaches both "head-to-head" and head-to-tail" dimers of vancomycin. Thus the cited references teach specifically-defined chemical structures.

Thus the examiner's position is that the references ***do*** indicate which parameters are critical and ***do*** provide direction as to which of many possible choices is likely to be successful. For example, Boeckh et al specifically teach combination therapy with vancomycin and ceftazidime and that this combination therapy is used to "cover a broad spectrum of gram positive and gram negative bacteria", Truett teaches the "linking of diverse antibiotic moieties via difunctional organic compounds" and Renoud-Grappin teaches the heterodimeric approach

for combination therapy, and improvements thereon by exploration of "other linkers and attachment sites for these linkers".

Appellant also argues that the teachings of Renoud-Grappin of exploration of "other linkers and attachment sites for these linkers" is not sufficient motivation, but only "suggests a possible avenue of research to be explored by those skilled in the art" (Brief, page 21). However, as in *In re O 'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988), the examiner determined that the instantly claimed invention would have been obvious over the prior art relied upon because the references contain a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful (this position is set forth in the rejection).

For example, Staroske discusses dimers of vancomycin and that in "light of recent reports of vancomycin-resistant bacteria" there is a "strong incentive for the development of more potent antibiotics" (page 4917, bottom). Truett and Renoud-Grappin show that dimeric, covalently linked drugs can be of value for treatments (especially for combination therapy) and Boeckh specifically shows combination therapy using combinations of antibiotics (specifically vancomycin and ceftazidime). Thus, as stated in the rejection, in view of the teachings of the references, one of ordinary skill would have been motivated to covalently link vancomycin with ceftazidime to create a broad spectrum antibiotic compound to fight antibiotic resistant strains. One of ordinary skill would also have had a reasonable expectation of success based on the fact that Staroske teaches linking chemistry for vancomycin.

Claims 46, 54, 57 and 58

Appellant addresses the fact that the particularly claimed limitations for claims 46, 54, 57 and 58 are not taught by the references on pages 22-23 of the Brief. As discussed in sections (6) and (7) above, claims 42, 44-46, 57 and 58 stand withdrawn from consideration as drawn to non-elected species. Thus, the arguments for claims 46, 57 and 58 are moot since these claims are not under examination. With respect to claim 54, the Truett reference clearly teaches a variety of "cephalosporins and related" compounds, see column 2, line 49 - column 3, line 14 of the patent.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Maurie Garcia Baker, Ph.D.
Primary Examiner
Art Unit 1639
(703) 308-0065

Conferees

PADMASHRI PONNALURI
PRIMARY EXAMINER

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600